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Toxic Substances

EPA

NEW CHEMICAL INFORMATION BULLETIN

Exemptions for Research and Development and Test Marketing

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Introduction

Section 5(h) of TSCA, 15 USC 2604(h), provides certain exemptions from the section 5(a) premanufacture notice (PMN) and significant new use notice requirements. Section 5(h)(1) authorizes EPA to allow persons, upon application, to manufacture ("manufacture" includes import) or process a new chemical substance or a chemical substance subject to a significant new use rule (SNUR) for "test marketing" purposes without complying with section 5(a). Section 5(h)(3) exempts substances that are manufactured in small quantities solely for research and development (R&D) from the section 5(a) notice requirements. No application is required for the exemption for R&D under section 5(h)(3).

EPA has received numerous questions about the scope of the exemption for R&D, the distinction between R&D and test-marketing activities, and the requirements associated with the two exemptions. The PMN rule provides definitions of R&D and test marketing for the purposes of section 5 exemptions. (See 40 CFR 720.3(cc) and 720.3(gg)). The general SNUR reporting requirements (40 CFR 721) incorporate the PMN definitions by reference. This New Chemical Information Bulletin provides more specific guidance to manufacturers and processors of new chemical substances and substances subject to SNURs.

Companies manufacturing and processing chemical substances under the R&D exemption should also be aware that EPA has published additional guidance on the R&D exemption in the Federal Register. Guidance has appeared in the preamble to the Inventory Reporting Requirements of December 23, 1977, (42 FR 64572); the notice entitled TSCA Chemical Substances Inventory; Removal of Inappropriately Reported Synfuel Substances of February 23, 1983 (48 FR 7683); and the preambles to the proposed and final revisions of the PMN rules published in the FEDERAL REGISTER on December 27, 1984 and April 22, 1986 (49 FR 50201, and 51 FR 15096).

Research and Development

A. Statutory Authority

Section 5(h)(3) exempts manufacturers and processors of chemical substances subject to TSCA from the notice requirements of section 5(a) if they manufacture or process the substances

"only in small quantities solely for the purposes of scientific experimentation or analysis, or chemical research on, or analysis of such substance, or another substance, including such research or analysis for the development of a product."

B. What is R&D, and What Chemical Substances May Be Considered R&D Substances?

1. R&D activities can be distinguished by their special purpose. Activities are considered R&D if they are intended solely as scientific experimentation, research, or analysis. R&D includes:

   - o synthesis of new chemical substances
   - o analysis, experimentation or research on new or existing chemical substances.

   In the course of R&D activities, professional researchers using the substances must be engaged in collecting information about and monitoring tests of the chemical substances being studied or developed. General distribution of chemical substances to consumers does not constitute R&D.

2. Chemical substances used exclusively for R&D are eligible for the R&D exemption if their manufacturers meet all the requirements associated with the exemption. (See discussion of requirements below). The substance must either be the focus of R&D itself, or be used in an R&D activity focussing on another chemical substance. The latter category encompasses reagents, chemicals to be used as standards for chemical analysis in laboratories, and intermediates used solely to produce R&D substances, including intermediates used in the production of pesticides used exclusively for R&D.

3. The purpose of R&D is distinct from test marketing. R&D focuses on the analysis of the chemical or physical characteristics, the performance, or the production characteristics of a chemical substance, a mixture containing the substance, or an article. Test marketing focuses on customers' acceptance of a chemical substance, and the probable demand for a product in a market where it will be competing with other goods.

4. R&D encompasses a wide range of activities which may occur in a laboratory, pilot plant, commercial plant outside the research facility, or at other sites

appropriate for R&D. The following activities which test the physical, chemical, production, and performance characteristics of a substance may be considered as R&D:

- o Chemical synthesis and physical/chemical properties testing in the laboratory.

- o Health and environmental effects testing.

- o Tests or demonstrations of equipment or production processes, which typically take place in pilot facilities, but may also involve production in full-scale commercial runs (e.g., testing a new chemical to ascertain whether it can be produced in commercial scale equipment, or testing a new or modified process to determine process capabilities such as yield, uniformity, or process scale-up).

- o Efficacy and performance tests (e.g., testing of color fastness of a dye, or the efficiency or lifetime of a new catalyst in a chemical manufacturing process).

- o Consumer panel testing of the performance characteristics of a new chemical substance.

  - Because such testing could involve broad exposures to new chemical substances, manufacturers and importers should be sure that they:

    -- Consider the activities of the consumer panel in any assessment of risks.

    -- Notify panel members of the potential for risks in a manner that adequately informs them.

    -- Provide the services of a technically qualified individual who will supervise the tests directly in a manner which offers panelists no less protection than would be provided to workers engaged in R&D in a laboratory.

  - EPA encourages manufacturers and importers to check with the Office of Toxic Substances to determine whether their consumer panel testing activities comply with the requirements of the rule.

C. Summary of Requirements

1. Although manufacturers of R&D substances are exempt from submitting a PMN for those substances, they must meet certain requirements set forth in section 5(h)(3) and the PMN rule. These requirements are listed in Table I and discussed below.

TABLE I
REQUIREMENTS FOR R&D EXEMPTION

Requirement	Requirements under 40 CFR 720	Associated Definitions
Production of small quantities	720.36(a)(1)	720.3(cc)
Supervision by a technically qualified individual	720.36(a)(3)	720.3(ee)
No general commercial use	720.36(d)	
Evaluation of risks	720.36(b)	
Notification of risks	720.36(a)(2) 720.36(b)(2) 720.36(c)	
Notification of the requirement that the substance be used only for R&D	720.36(c)(2)	
Recordkeeping	720.78(b)	

2. EPA has proposed to amend general provisions for SNURs (40 CFR 721, Subpart A) to adopt provisions similar to 40 CFR 720.36. Processors and their activities would be added. Until any amendments are promulgated, manufacturers and processors should follow 40 CFR 720.36 when conducting R&D activities with a chemical substance that is subject to a SNUR. (See 51 FR 15104 for the proposed amendments.)

D. Small Quantities

To qualify for the R&D exemption the substance must be manufactured or processed only in "small quantities," i.e., in quantities "that are not greater than reasonably necessary" for R&D purposes (40 CFR 720.3(cc)).

1. EPA has not attempted to define "small quantities" quantitatively. The Agency's definition of "small quantities" recognizes that the quantity of a chemical substance needed for legitimate R&D activities varies considerably with the category of substance, the use of the substance, and the nature and stage of R&D (e.g., 80,000 barrels of crude shale oil produced in a pilot plant operation, 500 pounds of a resin produced for performance testing, and 1 pound of a dye additive developed at the laboratory stage may all qualify as "small quantities" relative to the respective commercial activity).

2. Manufacturers may in some cases produce excess material for R&D without violating the requirement that only small quantities be produced. For example, a test of process conditions may lead to the production of more of a final product than is strictly necessary for efficacy testing; similarly, batch processing may lead to production of more of a substance than is needed for performance testing. The disposition of such excess material is discussed in section 720.36(d)&(e) of the PMN rule, and in part G below.

3. Manufacturers of living microorganisms will not qualify for the exemption for small quantities used exclusively for R&D. Such manufacturers should consult EPA's Statement of Policy on Microorganisms Subject to the Federal Insecticide, Fungicide and Rodenticide Act and the Toxic Substances Control Act, 51 FR 23313, June 26, 1986, especially page 23330.

E. Direct Supervision by a Technically Qualified Individual

A technically qualified individual must directly supervise all stages of the R&D activities that occur under the exemption for R&D. Section 720.3(ee) of the PMN rule defines such an individual as a person whose education, training, or experience, or a combination of these factors, prepares him or her to appreciate the risks from exposure to a chemical substance and to minimize such risks.

There is no requirement that a technically qualified individual have professional certification or be physically present during testing, and more than one such individual may supervise activities involving a particular chemical substance. However, the manufacturer or importer must provide all individuals engaged in R&D with direct supervision that offers them the same level of protection as offered to workers engaged in R&D in a laboratory.

F. Sale of R&D Substances

1. To be eligible for the R&D exemption, chemical substances must be produced exclusively for R&D. No substance produced under the exemption for R&D or mixture containing that substance may be sold or used for any non-R&D commercial purpose, except those listed in section G below, unless the substance has completed PMN review, is granted a test market exemption, or qualifies for a low volume exemption under 40 CFR 723.50.

2. Substances sold for exclusively R&D purposes are eligible for the R&D exemption. Manufacturers and processors may derive compensation from the sale of substances on which R&D will be conducted, or from the sale of substances such as laboratory reagents, chemical standards for analysis in laboratories, or intermediates to be used in the production of R&D chemicals, without being subject to section 5(a) notification requirements.

G. Use, Sale, and Disposal of Residual R&D Material

Surplus R&D material which remains after R&D activities are complete may be disposed of, sold, or used in several ways without triggering PMN requirements. In each case, manufacturers and processors must be able to demonstrate that the amounts of R&D substances produced were no greater than necessary for R&D purposes, and they must also evaluate the potential risks associated with the use of the R&D substance.

EPA permits the disposal of small quantities of R&D substances as wastes, i.e., in landfills or by blending small quantities of R&D material into an industrial process stream, such as a refinery stream. All disposal must be in accordance with local, state, and federal regulations, and any regulations under the Resource Conservation and Recovery Act that may apply.

Under §720.36(d)&(e) the following commercial uses are allowed without filing a PMN:

a. The sale or commercial use of substances or mixtures containing the R&D substance only as an impurity, if the substances were generated in the course of legitimate R&D (i.e., material produced through use of R&D chemical substances as intermediates or process aids).

b. The sale or commercial use of articles incorporating an R&D substance, if the articles were produced in the course of legitimate R&D.

   - o EPA considers an item to meet the definition of an "article" if it is manufactured in a specific shape or design for a specific end use application and this design is maintained as an essential feature in the finished product. (See definition in 40 CFR 720.3(c).)

   - o Examples of articles include dyed carpets, printed paper, moldable plastic sheets, and painted automobiles. The category of articles does not include mixtures or liquids, such as paint, or items whose shape is not maintained in a final product, such as metal ingots or plastic beads which are subsequently melted and molded into articles.

c. Burning of residual R&D substances as fuels.

d. Reacting or otherwise processing residual R&D material to form other chemical substances for commercial use. This includes such activities as the extraction of component chemical substances, or reacting a chemical substance to form other chemical substances for commercial use.

Any other commercial use of excess material produced during legitimate R&D is not allowed until manufacturers submit a PMN for the chemical substance, and the review period expires. Manufacturers may then make non-R&D commercial use of existing inventory without submitting a notice of commencement of manufacture (NOC). They must submit the NOC when the substance is first manufactured for non-R&D commercial purposes, and not before that time.

H. Evaluation and Notification of Risks

Section 5(h)(3) of TSCA requires manufacturers and processors to notify persons engaged in R&D of any risk to health which may be associated with the substance. Section 720.36 of the PMN rule

describes the information which the manufacturer must review to evaluate risks, establishes an exemption for laboratories using prudent laboratory practices, and prescribes the method of notification appropriate to different situations. In general, manufacturers must review information in their possession or control, and final rules issued under sections 4, 5, and 6 of TSCA to determine risks to health associated with the R&D substance. Table II outlines the requirements for evaluation and notification of risks. (Manufacturers and processors of substances subject to SNURs should also perform this review.)

EPA has not published regulations or guidelines specifying prudent laboratory practices, but manufacturers and processors should follow procedures established to control exposure to known toxic substances. For guidance, they should consult such handbooks as: National Research Council, "Prudent Practices for Handling Hazardous Chemicals in Laboratories," National Academy Press (1981); and U.S. Department of Health and Human Services, "NIH Guidelines for the Laboratory Use of Chemical Carcinogens," Washington, D.C., Government Printing Office (May 1981).

TABLE II
REQUIREMENTS FOR NOTIFICATION OF RISKS

Who must be Notified	Method of Notification	Content of Notification	Authority
Persons employed by a Firm for R&D Work	Any appropriate means	Risks associated with R&D substance*	720.36(a)(2)
Persons not in a firm's employ to whom it distributes R&D substances	In writing	Risks associated with R&D substance* Requirement that substance be used only for R&D	720.36(c)(2)

* In the case of workers in laboratories using prudent laboratory practices, or distribution from one such laboratory to another, EPA does not require evaluation of risks.

I. Recordkeeping Requirements

The PMN rule has established recordkeeping requirements to document compliance with certain key requirements of the R&D exemption. These requirements are summarized in Table III. Manufacturers must keep records documenting compliance with the requirements imposed by the exemption for 5 years.

In addition to the specific records required by the rule, manufacturers and processors who conclude they are exempt from section 5(a) notice requirements for a chemical substance used for purposes of R&D should be prepared to justify the nature and scope of their activities. They bear the burden of proving their eligibility for the R&D exemption, should a question arise concerning their compliance with the general requirements for PMN, a SNUR, or the exemption for R&D.

TABLE III
RECORDKEEPING REQUIREMENTS

Who Must Keep Records	Requirement	Authority
All manufacturers using the R&D exemption (except labs using prudent lab practices)	Copies of or citations to information reviewed to determine risks Documentation of the nature & method of risk notification	720.78(b)(1)(i) & (ii)
Labs using prudent lab practices	Documentation of prudent lab practices	720.78(b)(iii)
Manufacturers distributing R&D substances to persons outside their employ	Names and addresses of those who received substance Identity of substance Amount distributed Copies of written notification	720.78(b)(iv)
Producers of more than 100 kg/year	Record of identity of substance Production volume Disposition	720.78(b)(2)

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Test Marketing

A. Application and Approval Process

1. Section 5(h)(1) allows EPA, upon application, to exempt a manufacturer or processor from the requirements of section 5(a) for the manufacture ("manufacture" includes import) or processing of a substance for test marketing purposes.

2. To approve a test marketing exemption application, EPA must find, on the basis of a showing made by the applicant, that the test marketing of the substance will not present an unreasonable risk of injury to health or the environment. While applications need not be submitted in any specific form, EPA will not approve the application unless it meets the section 5(h)(1)(A) requirement that the applicant make a showing, "satisfactory to the Administrator," that the test marketing presents no unreasonable risk.

3. Section 5(h)(6) of TSCA requires EPA either to approve or to deny a test marketing exemption application within 45 days of its receipt, and to publish a notice of approval or denial in the FEDERAL REGISTER.

B. Scope of Test Marketing

Test marketing is described in the PMN rule, §720.3(gg), and the Inventory Reporting rule, §710.2(bb), as the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

Test marketing differs from R&D in the following ways:

1. Test marketing must be approved by EPA before it may occur. In any test marketing activity, the amount of material produced and distributed, the number of potential customers to whom it is distributed, and the time period of the test must be specified to EPA in advance of distribution.

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2. Test marketing involves distribution of a chemical substance in commerce to a defined market to evaluate demand for, or customers' acceptance of, the substance being tested. R&D involves monitored tests of the physical, chemical, production or performance characteristics of a substance.

3. Test marketing activities need not meet the requirements of the exemption for R&D in 40 CFR §720.36 and §720.78.

C. Simultaneous Submission of Test Market Exemption Applications (TMEAs) and PMNs

A number of TMEAs have been accompanied by PMNs for the same substance. EPA is concerned that the simultaneous submission of a TMEA and a PMN for the same substance might represent an effort by the submitter to obtain PMN review of a chemical substance in 45 days, rather than the 90 days provided by section 5(a) of TSCA. To discourage such an approach, EPA will closely examine simultaneous submissions to determine if genuine test marketing activity is involved; if it is not, the application will be denied.

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FOR ADDITIONAL INFORMATION

For further information on TSCA section 5(h)(3) and test-marketing exemptions and for copies of future New Chemical Information Bulletins contact:

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